

REMARKS

Claims 1-3, 9, 10, 12, 14-18, 28, 29, 31-35, 37-42, 44-49, 52 and 53 are pending in the application. Claim 41 has been withdrawn from consideration due to a restriction requirement.

Claim 39 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite. The applicant traverses the rejection as follows. The Examiner states the linear arrangement as illustrated appears parallel to the head portion (rather than the claimed shaft portion) and angled with respect to the shaft portion. While this is accurate for many of the embodiments, the Examiner is referred to Fig. 31, which best illustrates that for the nail-plate embodiment of the invention the plurality of elements for supporting the bone will be attached to the head portion with the attachment locations in a substantially linear arrangement parallel with the shaft portion.

Claim 44 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite. The claim has been amended to correct the antecedent basis issue. Similar correction has also been made to claim 42.

Claims 37-40, 42, 44-50, 52 and 53 stand rejected as anticipated by or obvious over U.S. Pat. No. 5,364,399 to Lowery. Claim 37 has been amended to include the limitation of claim 38. As such, claim 37 now requires:

at least three elements for supporting the bone extending from said lower surface of said head portion, said elements attached to said head portion in a linear or

smooth curve arrangement and being obliquely angled relative to each other and none of said elements converging in angle toward another element.

Thus, the claims, as amended, require at least three bone supporting elements attached in linear or smooth curve arrangement to the plate. This is not shown or suggested by Lowery. The Examiner states that Lowery shows two screws, but can include more than two screws. Nevertheless, Lowery fails to teach or suggest the claimed limitation for the following reasons. Lowery states, at col. 3, lines 22-29:

The plate 20 of the present embodiment includes a number of screw bores 27 defined in the plate. In the preferred embodiment, two screw bores are oriented at each of the first end 23 and the second end 24. Thus, four such screw bores are included so that fixation screws mounted in the plate through these bores provide a solid quadrilateral fixation to the instrumented vertebrae.

Given that Lowery is an anterior cervical plating system, the use of pairs of holes is consistent with cervical application. Moreover, the fact that the holes are arranged in pairs spaced apart at the ends of the plate is not just an exemplar embodiment, but rather essential to the Lowery invention. This feature is included in the Abstract, as well as each of the claims of the patent and is consistent with cervical plates. Lowery provides no teaching or suggestion for a linear or smooth curve arrangement of at least three bone supporting elements.

Moreover, with respect to claim 38, it is noted that Lowery does not teach or suggest a linear arrangement of at least three support elements oriented generally parallel to said shaft portion.

Claims 49, 50, 52 and 53 have not been addressed by the Examiner with respect to the anticipation or obviousness rejection. In particular, in order to support a rejection of a claim under 35 U.S.C. § 102(b), “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Lowery reference cited by the Examiner fails to teach all of the elements of the claims, as it does not teach the elements that are pegs with a threaded head, and elements that are directly connected or threadably attached to the head portion. Furthermore, the claims are allowable for the reasons advanced above with respect to claim 37.

For the foregoing reasons, claim 37 and all claims dependent thereon are allowable over the art of record.

Claims 1-3, 9, 10, 12, 14-18, 28, 29 and 31-35 stand rejected as unpatentable over Lowery in view of any of Bono, Talos and/or Frigg. The applicant respectfully traverses the rejection for the following reasons.

Claim 1 requires, among other limitations, (i) a substantially rigid *T-shaped plate*, (ii) a head portion being *angled upward* relative to a shaft portion, (iii) *threaded holes* adapted to individually receive therein pegs having threaded heads, and (iv) the head portion defining a first surface area on a first side of said arrangement of threaded holes of said head portion, opposite said shaft portion, and a second surface area on a second side of said arrangement of threaded holes of said head portion which is on a same side as

said shaft portion, *said first surface area being larger than said second surface area*.

This combination of features is not shown or suggested by the cited art. Lowery fails to teach all of the italicized elements of the claim.

In Bono, the plate (i) is not T-shaped, (ii) does not include a head portion angled upward relative to a shaft portion, (iii) does not have threaded holes, but rather *non-threaded plate holes* 14 that receive threaded bushings 16, and (iv) does not include the defined relative sizes of first and second surface areas. Therefore, Lowery in view of Bono fails to provide a prima facie case of obviousness for claim 1 and all claims dependent thereon.

In Talos, the plate (i) is not T-shaped, (ii) does not include a head portion angled upward relative to a shaft portion, and (iii) does not include the defined relative sizes of first and second surface areas. Moreover, Lowery teaches away from a system in which the screw head is not capable of varying degrees of fixation between the vertebra and the plate, such as would be provided with a plate including threaded holes. In discussing the prior art, Lowery states:

[T]he Synthes locking plate accepts spinal screws at several locations at the ends and in the middle of the plate. In each case, the screws are not capable of varying degrees of fixation between the vertebra and the plate. In addition, the Synthes device utilizes a locking screw which is threaded into the expansion head of the vertebral fixation screw to lock the screw into the plate. This procedure requires a locking screw for every fixation screw, thereby lengthening and complicating the procedure. (col. 1, lines 56-65)

In Lowery, the desired amount of compression can be provided between the plate and vertebra, independent of any fixation between the screws and the plate, and only then the

screws are fixed relative to the plate with a set screw. Therefore, Lowery in view of Talos fails to provide a prima facie case of obviousness for claim 1 and all claims dependent thereon.

In Frigg, the plate (i) is not T-shaped, (ii) does not include a head portion angled upward relative to a shaft portion, and (iii) does not include the defined relative sizes of first and second surface areas. Moreover, the same reasons provided above with respect to Talos and Lowery's teaching away from the use of threaded holes applies with respect to the combination of Lowery in view of Frigg. Therefore, Lowery in view of Frigg fails to provide a prima facie case of obviousness for claim 1 and all claims dependent thereon.

Moreover, with respect to each of the references, the dependent claims include additional limitations that are not shown or suggested by the art.

Claim 9 has been amended to clarify that shaft portion is angled out-of-plane relative to the head portion (as shown, e.g., in Fig. 5 with respect to angle ϕ). Claim 9 includes, among other limitations, (i) a plate with a *shaft portion angled out of plane relative to said head portion*, (ii) said head portion having upper and lower surfaces and defining a plurality of *threaded holes* adapted to individually receive therein pegs having threaded heads, (iii) the *threaded holes defining a plurality of axes which are oblique and divergent* relative to each other, and (iv) at least one *threaded hole which is oblique relative to the lower surface generally surrounding its corresponding threaded hole*.

This combination of features is not shown or suggested by the cited art. Lowery fails to teach all of the italicized elements of the claim. None of the cited references teaches a plate with a shaft portion angled out of plane relative to the head portion. Such configuration would defeat use of the plate for cervical applications and thus would not be obvious to provide to a Lowery-type plate. Therefore, claim 9 and all claims dependent thereon are allowable over the art of record.

Claim 28 has been amended to define the arrangement of the threaded holes. Claim 28, as amended, includes among other limitations, a plate portion and a shaft portion, with the plate portion including four threaded holes *in linear or smooth curve arrangement*, with the threaded holes defining *four axes which diverge away from each other* relative to the lower surface. As discussed above in relation to claim 1, Lowery teaches an arrangement of four non-threaded holes arranged in a quadrilateral (and also teaches two threaded holes for set screws). Only two holes with divergent axes are in a linear arrangement, and such holes are non-threaded. Bono also teaches non-threaded holes (which can be provided with bushings) and shows that three such non-threaded holes can be provided in linear arrangement. Talos and Frigg teach threaded holes, but all such holes are parallel. Moreover, as discussed above, Lowery teaches away from the use of threaded holes. Therefore, claim 28 and all claims dependent thereon are allowable over the art of record.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain

outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David S. Jacobson', with a stylized flourish at the end.

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